

OCT 7 - 2005

Advanced Monitored Caregiving Inc.
510(k) submission
AMC System
Overview and Product Description
June 3, 2005

510(k) summary

1. Submitter Information

Name: Advanced Monitored Caregiving Inc.

Address:

1729 E. 12th St
Brooklyn NY 11229

Telephone Number: 718-645-2273
Fax Number : 718-998-9247

Contact person:

Dr. George Myers
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Tel.: 201-727-1703
Fax: 201-727-1708

Date prepared: June 3, 2005

2. Name of Device

Trade Name: AMC System

Common Name: Central station for home medical parameters
measurement devices and transtelephonic digital transmission system

Classification name: Telephone Electrocardiographic transmitter and
receiver (870.2920/74DXH)

3. Equivalent legally- marketed devices:

Aerotel MPM, K041854
RemoteNurse, K041308
Cybernet Medstar K020534

4. Description

The AMC System receives data from cleared home measurement devices via an intermediary organization, stores the information in databases, and produces reports for patients and physicians that can be viewed on the Internet by means of secure transmission methods. The AMC system has no direct interface with patients or patients' measuring devices.

The AMC system performs no diagnosis. It stores the received data in the patient's file as received from intermediate organizations, and generates reports in the form of diagrams, data sheets, histograms and scatter diagrams (where applicable).

The AMC system allows the patient and his doctor to access the patient's data via the Internet by use of secured password-protected access codes. These codes (User name and password) are assigned by the AMC system..

5. Intended Use

The Advanced Monitored Care ("AMC") AMC System is intended to be used in conjunction with home patient measuring devices to send the measured parameters from a patient's home to a central computer via an intermediary organization, where reports can be generated for the physician and data can be reviewed over the Internet by physicians and patients.

6. Performance Data

Non – clinical tests

The software for this product has undergone extensive validation testing. The interfaces with the intermediary organizations are all tested for compatibility.

Clinical tests

The AMC system uses the same technology as the predicate devices, and thus no clinical tests are required. All home measurement devices are FDA-cleared..

7. Conclusion

The AMC System monitoring system is equivalent in safety and efficacy to the legally-marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 7 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Monitoring Caregiving Inc.
c/o Mr. George Myers
Medsys, Inc.
377 Route 17S
Hasbrouck Heights, NJ 070604

Re: K051544

Trade Name: Vital Caregiving System
Regulation Number: 21 CFR 870.2920
Regulation Name: Transmitters and Receivers, Electrocardiograph, Telephone
Regulatory Class: Class II
Product Code: DXH
Dated: September 09, 2005
Received: September 12, 2005

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. George Myers

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051544

Indications for Use Form

Device Name: AMC System

Indications for Use:

The AMC SYSTEM is indicated when a physician wants to periodically measure data of chronically-ill home patients via home monitoring devices connected via wired or wireless facilities to a central station, where reports can be generated and viewed via a Web browser by authorized personnel (e.g. physicians, care givers, and patients). The system is not intended to provide real-time data or real-time monitoring.

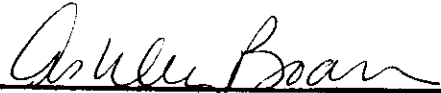
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051544